

## PATENT

Application No.: 10/078,622

Paper Dated: May 17, 2005

Attorney Docket No.: 126381.00901

## REMARKS

Claims 1-8 and 10-24 are pending in this application. Claims 11 and 12 have been amended to attend to minor typographical informalities. No new matter has been added.

**35 U.S.C. §102(e) Rejections**

Claims 1, 5, 6, 8, 10 and 13-24 stand rejected under 35 U.S.C. §102(e) for anticipation by U.S. Patent No. 6,786,904 to Döscher et al. (hereinafter "Döscher"). Applicants have concurrently filed a Petition for Unintentionally Delayed Claim of Priority to amend the specification of the present application to claim priority to U.S. Patent Application No. 10/044,475 to Döscher. Applicants submit that the claim of benefit is proper as the prior-filed non-provisional application is co-pending and includes a common inventor. Applicants believe that the concurrently filed Petition should perfect their claim for priority and therefore overcome the U.S.C. §102(e) rejection based on Döscher.

Claims 1-7, 10, 13-15 and 20-24 stand rejected under 35 U.S.C. §102(e) for anticipation by U.S. Patent No. 6,179,789 to Tu et al. (hereinafter "Tu").

Tu discloses an ablation apparatus system. The system includes a vascular stent, a detachable conducting wire means and a radiofrequency current generating means. The vascular stent includes a non-radioactive elongated metallic tube with a thin coating having dispersed therein a radioactive substance on an exterior surface of the tube. The radiofrequency current generating means generates radiofrequency current and heat within the tissue, with the radiofrequency current transmitted to the vascular stent through the detachable conducting wire means to allow the radioactive substance to diffuse more quickly into the heated tissue for prolonged radiotherapy for tissue treatment.

The present claimed invention is generally directed to an implant implantable member or device for delivery of a drug or a method of delivering a drug to a body. The implant includes an implant body and a drug material in contact with the implant body. The implant body is capable of being heated by exposure to an electromagnetic field having a frequency below about 1 MHz. The drug material is substantially effective when the implant is heated by exposure to the electromagnetic field and heat energy from the implant heats the drug material.

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Tu fails to teach or suggest an implant, implantable member or device as recited in the independent claims of the present claimed invention. In particular, Tu fails to teach or suggest an implant for delivery of a drug comprising an implant body capable of being heated by an exposure to an electromagnetic field having a frequency below about 1 MHz as recited in independent claim 1. Tu teaches resistive heating, i.e. direct electrical current, using a detachable conducting wire means as the heating mechanism. In particular, Tu teaches using radiofrequency energy as recited in column 7, lines 17-19, for example, which states that thermal energy is provided by radioactive substances and, therefore, Tu clearly does not teach inductive heating as recited in independent claim 1 of the present invention. The present claimed invention utilizes induction heating with an electromagnetic field exposed to an implant body. Accordingly, Tu does not teach or suggest heating by exposure to an electromagnetic field as recited in independent claims 1, 6, 13, 14, 15, 20 and 21. Applicants respectfully request reconsideration of the rejections of independent claims 1, 13, 14, 15, 20 and 21.

Claims 2-5 depend directly from and add further limitations to independent claim 1 and are deemed to be allowable for the same reasons in connection with independent claim 1. Applicants respectfully request reconsideration of the rejection of claims 2-5.

Claims 7 and 10 depend directly and indirectly from and add further limitations to independent claim 6 and are deemed to be allowable for the same reasons in connection with independent claim 6. Applicants respectfully request reconsideration of the rejection of claims 7 and 10.

Claims 22 and 23 depend from and add further limitations to independent claim 21 and are deemed to be allowable for the same reasons in connection with independent claim 21. Applicants respectfully request reconsideration of the rejection of claims 22 and 23.

**35 U.S.C. §103(a) Rejections**

Claims 2-4 and 7 are rejected under 35 U.S.C. §103(a) for obviousness over Döscher in view of Tu. The Examiner contends that it would have been obvious to use drug delivery mechanism taught by Tu and the device and method of Döscher. Applicants respectfully disagree. Under 35 U.S.C. §103(c)(1), subject matter developed by another person, which qualifies as prior art under 35 U.S.C. §102(e) shall not preclude patentability under 35

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U.S.C. §103(a) if the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. Applicants direct the Examiner's attention to the fact that Döscher and the present application are both commonly assigned to Triton BioSystems, Inc. and therefore Döscher does not qualify as a 35 U.S.C. §103(a) reference. Additionally, as described above, Tu does not teach or suggest the present claimed invention. Moreover, claims 2-4 depend directly from claim 1. Independent claim 1 is not deemed obvious by Döscher in view of Tu and, therefore, claims 2-4 which add further limitations to independent claim 1 cannot be considered obvious. Moreover, claim 7 depends directly from claim 6. Independent claim 6 is not deemed obvious by Döscher in view of Tu and, therefore, claim 7 which adds further limitations to independent claim 6 cannot be considered obvious. Accordingly, Applicants respectfully request that the rejections of claims 2-4 and 7 be withdrawn.

Claims 1-8, 10 and 13-24 are rejected under 35 U.S.C. §103(a) for obviousness over U.S. Patent No. 6,451,044 to Naghavi et al. (hereinafter "Naghavi") in view of Döscher.

Naghavi discloses an ultrasonically heatable stent including at least one ultrasound-absorptive material characterized by an acoustic impedance greater than that of living soft tissue. The stent includes a coating having at least one ultrasound-absorptive material overlaying the stent framework and characterized by being heatable by ultrasound of a faster rate than living soft tissue. The Examiner contends that it would be obvious to use the frequency taught by Döscher with the methods of Naghavi. Applicants respectfully disagree.

Naghavi does not teach or suggest using an electromagnetic field for heating as recited in independent claims 1, 6, 13, 14, 15, 20 and 21. Naghavi rather teaches heating stents by ultrasound (column 13, lines 30-31). The present invention and independent claims are directed to heating by the use of induction heating, specifically by exposure to an electromagnetic field. Accordingly, Naghavi does not teach or suggest heating by exposure to an electromagnetic field. Naghavi also fails to teach or suggest exposing an implant to an electromagnetic field having a frequency below about 1 MHz. Additionally, the coating disclosed in Naghavi requires an ultrasound-absorptive material and requires ultrasound energy for heating the coating in addition to heating the stent. Thus, in Naghavi both the stent and the coating are each heated independent of each other, whereas in the present invention the implant

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is heated which, in turn, heats the coating, thereby requiring only heating of the stent. Further the Applicants contend that the frequency of the inductive heat of the present claimed invention is preferably below 1 MHz. Under 1 MHz, the body tissue is generally opaque for radio frequency inductive heating, and above that frequency, the body tissue absorbs the energy and is heated himself. Contrary to this the radiofrequency current of Naghavi is preferably within the range of 50 to 2000 kHz.

As indicated above, Döschner is commonly assigned and can not be used to cure the deficiencies of Naghavi. Accordingly, Applicants respectfully request reconsideration of the Examiner's rejections to independent claims 1, 6, 13, 14, 15, 20 and 21.

Claims 2-5, 7-8 and 10, 16-19, and 22-23 depend directly and indirectly from and add further limitations to independent claims 1, 6, 15, and 21, respectively, and are deemed to be allowable for at the least the same reasons in connection with independent claims 1, 6, 15, and 21. Applicants respectfully request reconsideration of the rejection of claims 2-5, 7-8, 10, 16-19 and 22-23.

Claims 11 and 12 are rejected under 35 U.S.C. §103(a) for obviousness over Döschner or Naghavi. The Examiner contends that using a stent to both deliver and stop drug delivery at specific temperatures using a controlled electromagnetic field exterior to the body would have been an obvious modification to either Döschner or Naghavi. Applicants respectfully disagree. As discussed above, Döschner is commonly assigned and, therefore, does not qualify as a §103(a) reference and Naghavi fails to teach using an electromagnetic field for heating a drug material and, therefore, does not render claims 11 and 12 obvious. Applicants respectfully request reconsideration of the rejections of independent claim 11.

Claim 12 depends from and adds further limitations to independent claim 11 and is deemed allowable for the same reasons in connection with independent claim 11. Applicants respectfully request reconsideration of the rejection of claim 12.

In view of the foregoing remarks, claims 1-8 and 10-24 are believed to be in condition for allowance. Reconsideration of the Examiner's rejections and allowance of claims 1-8 and 10-24 are respectfully requested. Should the Examiner have any questions regarding these remarks, the Examiner is invited to initiate a telephone conference with the undersigned.

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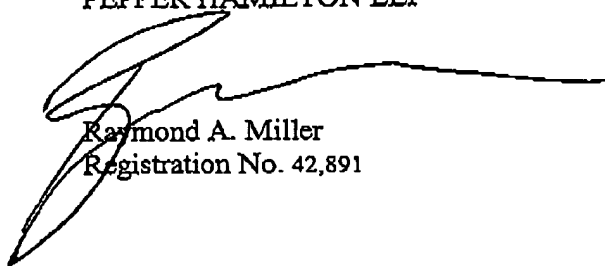
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Although Applicants believe no fees are due, the Commissioner is hereby authorized to charge Deposit Account No. 50-0436 for any fees that may be due in connection with this response.

Respectfully submitted,

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